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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/380,203	04/25/00	DE LA MONTE S	0609.4370001

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EXAMINER	
WHITEMAN, B	
ART UNIT	**PAPER NUMBER**
1633	14

DATE MAILED: 06/01/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/380,203	Applicant(s) DE LA MONTE ET AL.	
	Examiner Brian Whiteman	Art Unit 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04/25/00* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims *1-34* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

DETAILED ACTION

Claims 1-34 are pending and under consideration in the instant application.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-6 and 10-13, drawn to a DNA construct which comprises a DNA molecule of Seq. ID No. 1; DNA construct of claim 1 is contained within a vector; a host cell transformed with the DNA construct of claim 1; an *in vitro* method for screening a candidate drug that is potentially useful for the treatment or prevention of Alzheimer's disease.

Group II, claim(s) 7-9 and 14-16, drawn to a transgenic non-human animal, all of whose germ and somatic cells comprises the DNA molecule of Seq. ID No. 1; an *in vivo* method for screening a candidate drug that is potentially useful for the treatment or prevention of Alzheimer's disease.

Group III, claim(s) 17-32 and 34, drawn to antisense compositions corresponding to nucleotides 150-1139 of Seq. ID No. 1.

Group IV, claim(s) 33, drawn to a method for to treat or prevent dementia of the Alzheimer's type of neuronal degeneration comprising administering to an animal in need thereof an antisense oligonucleotide, a ribozyme, a triple helix-forming oligonucleotide or an ribonucleotide external guide sequence of any one of claims 17, 24, 26, 28, or 30.

Group V, claim(s) 33, drawn to a method for to treat or prevent neuroectodermal tumors, malignant astrocytomas, or glioblastomas, comprising administering to an animal in need thereof an antisense oligonucleotide, a ribozyme, a triple helix-forming oligonucleotide or an ribonucleotide external guide sequence of any one of claims 17, 24, 26, 28, or 30.

The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT rule 13.2, they lack the same or corresponding special features for the following reasons:

37 CFR 1.475(c) states:

"If an application contains claims to more or less than one of the combination of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present."

37 CFR 1.475(d) also states:

"If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and 1.476(c)."

37 CFR 1.475(e) further states:

"The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternative within a single claim."

In view of 37 CFR 1.475 (c), 37 CFR 1.475 (d), and 37 CFR 1.475 (e). Group I is considered the main invention to the product first mentioned in the claims, and the first recited invention drawn to other categories related thereto, e.g. a method of making, method of use.

Groups I-III are drawn to multiple distinct products that do not share the same inventive concept. The claimed invention of Groups I recite distinct materials that are neither require nor recited in the claimed invention of Group II and III, and thus have their own special technical features. For example, the transgenic non-human animal as claimed in Group II; the anti-sense compositions in Group III encompass structural materials that are distinct than the DNA sequence of Group I. Thus, it follows from the preceding analysis that the claimed inventions listed as Group I, Group II and Group III do not related to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2 they lack the same or corresponding special technical feature for the reasons set forth above.

In addition, the claimed inventions of Group I-V recite distinct materials and/or methods steps that are neither required nor recited in the claimed invention of Group I, and thus lack the same or corresponding technical feature for the following reasons:

The special technical feature of Group I is considered to be a method *in vitro* method for screening a candidate drug comprising contacting a candidate drug with the host cell line of claim 5.

The special technical feature of Group II is considered to be a method *in vivo* method for screening a candidate drug comprising administering a candidate drug to the transgenic animal of claim 7.

The special technical feature of Group IV is considered to be a method for to treat or prevent dementia of the Alzheimer's type of neuronal degeneration.

The special technical feature of Group V is considered to be a method for to treat or prevent neuroectodermal tumors, malignant astrocytomas, or glioblastomas.

Accordingly Groups I-V are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

The inventions listed as Groups I-V do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the reasons set forth above.

As the technical feature linking the members of the listed in claim does not constitute a special feature as defined by PCT Rule 13.2, particularly since the compound(s) and/or substance(s) listed in the claims do not share a structural feature in common with respect to their site of action. Thus, the requirement of unity of the invention is not fulfilled.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their divergent subject matter, restriction for examination purposes as indicates is proper.

Thus it would be unduly burdensome for the examiner to search all of the claimed inventions being sought in the pending claims.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ms. Tracey Johnson whose telephone number is (703) 305-2982.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (703) 305-0775. The examiner can normally be reached on M-F, (730-400 EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Clark can be reached at (703) 305-4051.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 305-7401.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

DAVE T. NGUYEN
PRIMARY EXAMINER

Brian Whiteman
Patent Examiner. Group 1633
May 24, 2001